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## **Should There Be an Obligation of Disclosure of Origin of Genetic Resources in Patent Applications? – Learning Lessons from Developing Countries<sup>\*</sup>**

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### **Abstract**

*In the lead-up to two meetings in June 2005 which will address the question of whether there should be an obligation of disclosure of origin of genetic resources in patent applications, this paper uses the on-going international policy debate in this area as a platform both to make some specific observations about this particular issue, and to offer some comments on the broader question which it raises of how the intellectual property world integrates with other legal and ethical regimes.*

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<sup>\*</sup> **N.B.** An earlier version of this paper was delivered at a Roundtable meeting entitled 'Biotechnology and Intellectual Property in Developing Countries' which took place in the Faculty of Law, University of Buenos Aires, 26 April 2005.

This version was submitted for translation purposes on 3 May 2005. The reader should therefore be aware of possible developments in the period between submission and the two meetings mentioned in the Introduction below.

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## 1. Introduction

In the lead-up to two meetings in June 2005 which will address the question of whether there should be an obligation of disclosure of origin of genetic resources in patent applications,<sup>1</sup> I want to use the on-going international policy debate in this area as a platform both to make some specific observations about this particular issue, and to offer some comments on the broader question which it raises of how the intellectual property world integrates with other legal and ethical regimes. Let us start with this 'Big Picture' perspective.

## 2. The Evolving Relations of the IP world

I recently shared a platform at an international conference<sup>2</sup> with Dr Francis Gurry, Deputy Director General of WIPO, who offered the view that WIPO has "...no methodology whatsoever..." to tackle the interface between patent policy and public policy. He helpfully categorised the evolution of the patent system into three stages:

- Stage I (1886 – TRIPs): unimodular system; patent law's **own** policies drove the system
- Stage II (1992-1998): System begins to consider **its** impact on other policy areas
- Stage III (1998-present): More complexity and interaction; IP considered **from** other policy areas

The implication is that, underlying this evolution of interaction is an historical tendency for the patent system to be extremely insular. Moreover, despite far more interaction today than has ever occurred in the past, it is still possible to detect strong enduring reluctance to see, or accept, the patent system as part of a greater whole.

There is considerable evidence of this in the current debate on disclosure of origin of genetic resources in patent applications. While we have, at least, reached the stage of accepting – and agreeing<sup>3</sup> – the need to examine the dynamics between the patent system and the CBD regime, our policy options are very much constrained by an unwillingness in certain quarters to accept a **reality**: which is – the interconnectedness of the patent regime, not only to CBD, but, potentially, to many other legal and ethical frameworks.

But even among those who are more open to this reality, thinking in the area can often be task-oriented and driven, leaving us to speculate about the more wide-ranging implications of adopting any given set of policy options.

Thus, for example, the current flurry of activity on disclosure of origin stems from the invitation from the Conference of the Parties (COP) to the Convention on Biological

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<sup>1</sup> WIPO, *Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements*, 3 June 2005, and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Eighth Session, 6-10 June 2005.

<sup>2</sup> University of Cambridge, the Sasakawa Peace Foundation and the Japanese National Graduate Institute for Policy Studies, *Bioethical Issues of Intellectual Property in Biotechnology*, Tokyo, Japan, 6-7 September 2004.

<sup>3</sup> See, for example, the *Memorandum of Understanding* concluded between the CBD Secretariat and WIPO (Document WO/CC/48/2, 24 July 2002).

Diversity (CBD) to WIPO<sup>4</sup> to examine the issue in more depth, and most notably to do so in terms of the CBD objectives in Article 1; especially that of "...the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources ...". The resulting debate has therefore largely be framed – and delimited – by these boundaries.

By the same token, a survey of the member states' responses to the invitation – and the resulting WIPO first Draft Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications (Jan 2005)<sup>5</sup> – reveals a far greater range of expectations from the notion of introducing an obligation of disclosure of origin.

While the WIPO Draft Examination does a good job of collating and laying out the range of options that have been raised, it does a far less satisfactory job of equipping us to approach the policy debate in terms of the fundamentals in issue: that is,

- What, in essence, is at stake? And,
- What can we realistically expect of the patent system?

### **3. What is expected?**

Among others, the following expectations of a disclosure of origin obligation have been mooted:

- To fulfil properly existing disclosure requirements in patent law, viz, novelty and inventive step
- To acknowledge a link between the genetic resource and the invention
- To acknowledge a link between the genetic resource and the inventor
- As a means to monitor and sanction compliance with access and benefit sharing agreements, i.e. the CBD focus
- As a possible means to further the other objectives of CBD, namely, conservation and sustainable use
- As a means to verify and/or ensure compliance with other national laws, e.g. on prior informed consent (which may include an element of ethical review)
- There has even been discussion of measuring the 'rightfulness' of conduct to obtain/use genetic resources (even in the absence of any national legal prohibition) - which brings in a far more ethically-based perspective.<sup>6</sup>

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<sup>4</sup> The 'invitation' was in fact, first, to produce a Technical Survey on methods within the patent system for requiring disclosure relevant to genetic resources and traditional knowledge (COP Decision VI/24C, paragraph 4), and then more recently, "...to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications." (COP Decision VII/19E, paragraph 8).

<sup>5</sup> WIPO Secretariat, *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications: First Draft* (2005), available at: [http://www.wipo.int/tk/en/genetic/proposals/first\\_draft\\_examination\\_cbd\\_invitation.doc](http://www.wipo.int/tk/en/genetic/proposals/first_draft_examination_cbd_invitation.doc).

<sup>6</sup> See A.K. Gupta, *WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge*, pp.57-58, available at: [http://www.wipo.int/tk/en/publications/769e\\_unep\\_tk.pdf](http://www.wipo.int/tk/en/publications/769e_unep_tk.pdf).

#### 4. *Why such expectations?*

But we have to ask why there is such a range of expectations? The answer depends on what is expected. Some of these expectations are about the moral significance of the material or the people it has come from; others are about transparency of process; others are about assisting in furthering other objectives (such as those of the CBD), and others still are about a quasi-regulatory function to complement other regulation regimes.

We need to know – WHY – because a whole host of answers to other questions depend on this. For example, key questions that are raised in the Draft Examination include:

- **What** is the subject matter that is the focus on the obligation?

Well, it depends. Are we concerned about biological material because it is ‘living’, or are we concerned about the ‘value’ of the resource (in either monetary or moral terms)?

- **When** does the obligation of disclosure arise?

Well, it depends. Are we concerned to know the source of the genetic resource to determine its relationship to an invention, or is its source of significance in measuring ethical compliance in its acquisition and use? If the former, the obligation only arises when there is a sufficiently strong connection between resource and the invention per se. If the latter, arguably, the obligation may be triggered if the resource has been used at any point in the development of the invention.<sup>7</sup>

- **Which** consequences should flow from non-compliance?

The Draft Examination certainly acknowledges that ‘...consequences of failure to comply *may, in principle*, flow from reasons for the imposition of the requirement’. [emphasis added] But it only does so in passing. Yet, to my mind, this is the fundamental issue – there is no ‘*may*’ about. The principles at stake necessarily inform the practice. And I would suggest that we are far from clear about which principles are at stake.

#### 5. *How should we approach the debate?*

So how do we approach the debate and begin to answer these questions? Underlying many of the expectations – although not necessarily all – are notions of justice. It is at this point that the intellectual property lawyers leave in disgust: surely this notion is simply too abstract and indistinct to be helpful. But we have to remember that equity underpins the obligation of benefit sharing under CBD, and, closer to home for the IP lawyer, it is obvious that the relationship between ‘justice’ and ‘disclosure’ is, in fact, well known in the patent regime. It arises, of course, from the very nature of the regime itself, which is built on obligations of disclosure that are justified in large part because of ideas about when it is fair or just to grant or to deny a patent.

On a justice analysis, the substantive criteria for patentability require disclosure of all of the elements of invention necessary to allow an expert to reproduce it because it would be unfair to give a monopoly in the absence of a genuine and significant

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<sup>7</sup> Another obvious question is, which actions are to be monitored?

contribution to human knowledge; similarly, we test novelty through enabling disclosure because it is unacceptable to award a monopoly for something already invented.

We do not normally articulate the substantive criteria of patent law in this way – indeed, we (intellectual property lawyers) tend to talk of these as ‘technical matters’ – but notions of justice are there nonetheless.

This is not to suggest that this is a definitive analysis of substantive patent criteria, but it is to suggest that this is a meaningful interpretation of how we see existing disclosure obligations from within patent law. Moreover, we universally accept that non-compliance carries the severest of consequences, namely, refusal/revocation of a patent.

We are far less certain, and certainly far less agreed, about the impact of justice concerns from outside the patent system. But I would also suggest that this is largely because we do not conduct the debate paying sufficient attention to what those concerns are.<sup>8</sup>

The WIPO Technical Study suggested that the underlying key issue is how to characterise the necessary relationship between genetic resources/TK and an invention.<sup>9</sup> But responses from member states indicate a far greater range of concerns and expectations of a disclosure of origin obligation.

Fundamentally, then, we must be clear about what we want to achieve, and a focus on justice may be one means to ensure that the debate at least begins on a level playing field.<sup>10</sup> Moreover, if justice is at stake, it may assist in determining how this should be addressed.

## **6. How should we handle a disclosure of origin obligation?**

This brings us back to the issue of the interface of patent law with the wider world.

Gurry’s analysis of the policy history of the patent system as three distinct approaches is reflected, I believe, in the responses of WIPO member states to the Invitation by the COP of the Convention on Biological Diversity on Access to Genetic Resources and Disclosure Requirements in IP Rights Applications.

I would categorise these as follows:

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<sup>8</sup> The WIPO Draft Examination document acknowledges: ‘One way of characterizing the relationship [between genetic resources and disclosure requirements] may be to draw a link between inequitable behavior in one context or jurisdiction, and entitlement to exercise patent rights in another, where the patented invention is in some way a consequence of the inequitable behavior. Another way of defining the link would be to view the denial or invalidation of a patent right in one jurisdiction as a form of sanction for non-compliance with other laws. Some uncertainty surrounds this kind of mechanism in international policy debate, and further study may be necessary of approaches to enforcing non-patent legal requirements through the patent system., see note 5 above, para 74.

<sup>9</sup> Ibid, para 76.

<sup>10</sup> I favour this idea because it straddles fields (in the sense that it is a commonly understood and valued concept), it lies at the very heart of CBD, and because it is a common denominator in many of the concerns raised (even if it is not articulated as such). It is acknowledged, however, that it will not help to address all concerns. But then, maybe we should not expect too much of the obligation of disclosure of origin.

## 6.1 Separatists

First, we have the separatist group – which includes the United States and Australia – and which persists in a view of the patent regime as a world apart. For them, solutions must emerge outside patent law. This is a position which conveniently allows a principled stance to be taken in respect of ideas such as benefit sharing because – on this view – it then becomes someone else’s problem. My own view, for what it is worth, is that this is an outmoded, unrealistic, and increasingly unsustainable view of patent law. This is not to say, however, that some arguments advanced by this group are not valid, and we shall return to this below.

## 6.2 Revisionists

The second group are the revisionists – that is, those willing to revise the patent system in light of its impact on other policy areas. This approach is fine as far as it goes, but often it does not go far enough. For example, the proposals on the disclosure obligation which simply seek internal reform of the patent system perpetuate a view of disclosure as instrumental to existing intellectual property ends.<sup>11</sup> We have seen, however, a range of views on other ends that might be furthered by such an obligation, and these cannot be adequately addressed within established patent paradigms (if they are to be addressed at all).

By the same token, patent law can only give responses from within the limits of its own boundaries, being – a system concerned essentially with an economic right to monopoly of a market for a fixed period of time. And, as Australia has pointed out, refusal to grant a patent does not necessarily prevent commercialisation, although it may seriously hinder securing benefits for further distribution.

Yet, the ‘power’ of the patent system – in the sense of its unique contribution – essentially lies in the ability to grant or deny monopoly control. The EU position, however, rejects this as a policy solution. Its proposal seems, at first sight, revisionist in its acceptance of the need to include disclosure requirements in patent applications. Ultimately, however, it maintains a separatist stance by arguing that sanctions for non-compliance should arise outside the patent system. It seems to me that this robs their proposal of virtually all of its potential impact.

## 6.3 Integrationalists

We are left, then, with what I would call the integrationalists, who seek a far more holistic approach to the role and function of patent law. Most developing countries seem to adopt this approach, and I would join them. The stark reality we have to face up to, however, in seeking a more integrated approach between patent law and other legal and ethical systems, is the limitations of the patent system itself in terms of what it can realistically achieve. Beyond this, it is also important for this group to articulate what is expected of further integration between systems.

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<sup>11</sup> These measures include: a) requirements to disclose known TK when relevant prior art, b) requirements to disclose when TK holder may be ‘inventor’, c) requirement to disclose source/origin when access to material is required to enable invention, or d) under Budapest obligations. All and more of these are discussed fully in the Draft Examination and Technical Study documents.

The proposal from Brazil is typical of this approach and contains ambitious expectations of the disclosure requirement ranging from (1) an argument that it will improve patent examination standards, (2) through ensuring accurate attribution of inventorship, (3) and on ultimately to the view that "...it would constitute an important realization of the principle of equity".<sup>12</sup> Indeed, what unifies most of the reasons offered by Brazil is equity. What may divide them, however, is efficacy. The United States, for its part, argues that certain key objectives simply cannot be realised by including a disclosure of origin provision in patent law, viz, (1) access and equitable benefit sharing, (2) preventing misappropriation of genetic resources, and (3) preventing erroneously issued patents. If this is true, it rather puts an end to the matter. But we do not know if it is true, and there are now many examples of models in practice<sup>13</sup> – many albeit fairly new – from which sounds empirical data can be drawn.<sup>14</sup>

None the less, in terms of beginning to discern how to integrate better the patent system with other systems this points to an important factor, viz.:

- **EFFICACY:** when we articulate what we expect of further integration between systems, *efficacy* must be a crucial factor in identifying the nature of the relationship between patent law and other systems.
- **ADDITIONALITY:** To this I would add the criterion of *additionality* – by which I mean, we should ask: what, if anything, can a solution based in patent law bring to existing systems that does not already exist in those systems?<sup>15</sup> It seems to me that the main answer to this is the ‘power’ of the patent system mentioned above, namely, to grant or deny monopoly control.<sup>16</sup> For example, does the prospect of denying/revoking a patent provide an additional safeguard to interests surrounding genetic resources, albeit if it is only, or largely, in the form of the disincentive that the threat represents? I think that the position is definitely arguable, and it is for this reason that I find the EU proposal to be distinctly unhelpful in moving the debate forward.<sup>17</sup> The corollary, of course – if the incentive/disincentive analysis of intellectual property is accurate – is the risk of *detriment* that might arise if a regime deters on-going work using genetic resources.
- **USURPATION:** The patent system is not the regulation system nor vice versa, and we therefore must be careful to avoid illegitimate attempts to *transplant* functions of one system into another. There may, however, be much scope for *congruence* between the systems.

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<sup>12</sup> See, Brazil’s Position on the Principles and Methodology of Work that should be Employed in the Preparation of the Response by WIPO, 16 December 2004, p.3, available at: <http://www.wipo.int/tk/en/genetic/proposals/brazil.pdf>.

<sup>13</sup> For a recent comprehensive report and suggested model, see M Dross and F Wolff, *New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources: The Role of Certificates of Origin* (2005), available at: <http://www.oeko.de/oekodoc/233/2005-001-en.pdf>.

<sup>14</sup> See also the work of the UNU-IAS study acknowledging that we still do not know enough about the effectiveness of many approaches to date: <http://www.ias.unu.edu/research/certificatesoforigin.cfm>.

<sup>15</sup> This may alternatively be termed the need to *avoid redundancy*.

<sup>16</sup> There is also, of course, the possibility of transfer of rights upon a finding of illegitimate non-disclosure.

<sup>17</sup> The official line taken by the EU for rejecting this option was on grounds of fear of creating legal uncertainty.

- CONGRUENCE: the grant of a patent in the face of illegitimate acquisition of genetic resources may be seen as a form of state-sanctioned unjust enrichment, and on this analysis the issue is one of avoiding incongruity between regulatory and patent regimes. Congruence would suggest that each system should reflect and re-enforce the value preferences underpinning them in a manner that is true to the essential nature of those preferences.

This brings us back, then, finally, to the fundamental questions that I consider to be so important: what *are* our values in this debate, and is the patent system the best way to give expression to them?

I have suggested that justice is an important value in this context, not just for what it represents for its normative appeal, but also for what it can mean for policy development. If fundamentals such as justice are at stake this requires a far stronger response than may be justifiable in respect of other values.